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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,760	08/07/2001	Milan Mrksich	7814/45	1390

7590

12/20/2002

BRINKS HOFFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610

EXAMINER

CEPERLEY, MARY

ART UNIT PAPER NUMBER

1641

DATE MAILED: 12/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/923,760

Applicant(s)

MRKSICH ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-117 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-117 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

1) To aid the examiner in finding the references cited on form PTO-1449, applicants are requested to advise the examiner as to how many box(es) of references have been submitted along with the Information Disclosure Statement of March 04, 2002.

2) Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to alkane thiols, classified based on the complete structure of the final product, e.g. in numerous subclasses of classes 544, 546, 548, 549, 564, 560, and 568.
- II. Claims 8-15, drawn to disulfides, classified based on the complete structure of the final product (analogous to I. above).
- III. Claims 16-24, drawn to gold substrates with ligands attached, classified in class 436, subclass 525.
- IV. Claims 25-35, drawn to substrates with multiple ligands attached, classified in class 436, at least subclasses 527, 530, 531, and 528.
- V. Claims 36-39, drawn to a protein chip comprised of a reaction product of a ligand and a fusion polypeptide, classified in class 530, subclass 402.
- VI. Claim 40, drawn to a method of making a gold substrate containing an alkanethiol.
- VII. Claim 41, drawn to a method of making a substrate containing a disulfide.
- VIII. Claims 42-45, drawn to a method of making a protein chip containing a fusion polypeptide.
- IX. Claim 46, drawn to a method of making a protein chip using the substrate of claim 25.
- X. Claims 47 and 48, drawn to methods of assaying enzyme activity, classified in class 435, subclass 23.
- XI. Claim 49, drawn to a fusion product, classified in class 424, subclass 192.1.
- XII. Claim 50, drawn to a polynucleotides encoding a fusion, classified in class 435, subclass 91.1.

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- XIII. Claim 51, drawn to a vector, classified in class 435, subclass 91.4.
- XIV. Claims 52-56, drawn to host cells, classified in class 435, subclass 325+.
- XV. Claims 57 and 58 (presumably claim 58 is meant to be dependent from method claim 57 rather than "host cell" claim 52; the claim 57 "vector of claim 46" is inconsistent with the "protein chip" recited in claim 46), drawn to a method of making a vector.
- XVI. Claims 59-65, drawn to a method of determining enzyme activity using a protein chip.
- XVII. Claims 66-70, drawn to methods of analysis of antibodies, classified in class 436, subclass 518.
- XVIII. Claims 71-80, drawn to a method of immobilizing a fusion on a surface.
- XIX. Claims 81-98, drawn to a method of immobilizing a display moiety on a surface.
- XX. Claims 99-117, drawn to a method of attaching a polypeptide to a surface, classified in class 530, subclass 810.

3) The inventions are distinct, each from the other because of the following reasons which are given by way of example:

Inventions VIII and V (although of different scopes) might be viewed as related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the protein chip might be made by preparing an avidin derivative of the fusion polypeptide and contacting a biotinylated substrate with the avidin-fusion protein.

Inventions I and VI, for example, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the

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instant case the thiol functionality of the product of I could be reacted with an immunogenic protein to form an immunogenic conjugate useful in the preparation of antibodies specific for the ligand "T".

Inventions I and II, for example, are unrelated. Although the moiety -L-Q-T is the same for the structures of each of claims 1 and 8, the terminal functional groups -SH (claim 1) and "J-S-S-" (claim 8) provide compounds which are very different in chemical nature and function.

Inventions XI and I, for example, are unrelated. The ligand-linker conjugate of Group I is in no way related chemically or structurally to the fusion product of claim 49 (Group XI).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification requiring widely divergent searches in the patent and technical literature, restriction for examination purposes as indicated is proper. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Most of the inventions are unrelated to each other and involve very different patentability considerations. For example, a patentability determination for a compound of Group I would involve the determination of the novelty and unobviousness of the compound *per se independent of any utility of the compound*. The method of Group X, in contrast, would require a determination of the patentability of a method of assaying kinase activity which involves the use of a fusion peptide not included by the structure of claim 1. These patentability considerations are completely unrelated in nature.

4) Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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5) Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6) *The claims of each of Groups I-XX contain multiple patentably distinct species. For the election of any one of Groups I-XX, applicants must further elect a single disclosed species defined by the combination of a specific definition for EACH VARIABLE present in the claims. For example, if Group I is elected, applicants must elect a specific definition for each of variables L, Q and T as defined in claim 1; if Group XV is elected, applicants must elect a specific fusion polypeptide, substrate, and polynucleotide; if Group XVIII is elected, applicants must elect a specific "fusion", a particular "surface", and a "reactant ligand". Applicants are advised that the elected species, which will constitute the elected invention, will be examined on the merits along with all other species which are not patentably distinct from the elected species.*

Due to the multiple claimed inventions in this application, applicants are further advised to expect a possible further restriction and/or election requirement when this case is assigned to an examiner for prosecution on the merits after this initial restriction requirement.

7) Applicants are advised that in accordance with the court decisions in *In re Ochiai*, {71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995)} and *In re Brouwer* {77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996)}, in the event that a product claim is found to be allowable, a method of use claim *which is of the same scope as the allowed product claim* may be rejoined with the allowed product claim.

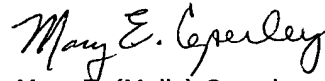
8) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE** at **(703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

December 17, 2002


Mary E. (Molly) Ceperley
Primary Examiner
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